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APPENDIX 3.8.4.

SURVEILLANCE FOR BOVINE SPONGIFORM ENCEPHALOPATHY

Article 3.8.4.1.

Introduction

1. Depending on the risk category of a country, *zone* or *compartment* with regard to bovine spongiform encephalopathy (BSE), surveillance for BSE may have one or more goals:
 - a) detecting BSE, to a pre-determined design prevalence, in a country, *zone* or *compartment*;
 - b) monitoring the evolution of BSE in a country, *zone* or *compartment*;
 - c) monitoring the effectiveness of a feed ban and/or other risk mitigation measures, in conjunction with auditing;
 - d) supporting a claimed BSE status;
 - e) gaining or regaining a higher BSE status.
2. When the BSE agent is present in a country or *zone*, the cattle population will comprise the following sectors, in order of decreasing size:
 - a) cattle not exposed to the infective agent;
 - b) cattle exposed but not infected;
 - c) infected cattle, which may lie within one of three stages in the progress of BSE:
 - i) the majority will die or be killed before reaching a stage at which BSE is detectable by current methods;
 - ii) some will progress to a stage at which BSE is detectable by testing before clinical signs appear;
 - iii) the smallest number will show clinical signs.
3. The BSE status of a country, *zone* or *compartment* cannot be determined only on the basis of a surveillance programme but should be determined in accordance with all the factors listed in Article 2.3.13.2. The surveillance programme should take into account the diagnostic limitations associated with the above sectors and the relative distributions of infected cattle among them.

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4. With respect to the distribution and expression of the BSE agent within the sectors described above, the following four subpopulations of cattle have been identified for surveillance purposes:
 - a) cattle over 30 months of age displaying behavioural or clinical signs consistent with BSE (clinical suspects);
 - b) cattle over 30 months of age that are non-ambulatory, recumbent, unable to rise or to walk without assistance; cattle over 30 months of age sent for emergency slaughter or condemned at ante-mortem inspection (casualty or emergency slaughter, or downer cattle);
 - c) cattle over 30 months of age which are found dead on farm, during transport or at an abattoir (fallen stock);
 - d) cattle over 36 months of age at routine slaughter.
5. A gradient is used to describe the relative value of surveillance applied to each subpopulation. Surveillance should focus on the first subpopulation, but investigation of other subpopulations will help to provide an accurate assessment of the BSE situation in the country, ~~zone or compartment. All countries should sample at least three of the four subpopulations.~~ This approach is consistent with Appendix 3.8.1. on general guidelines for animal health surveillance.
6. When establishing a surveillance strategy, authorities need to take into account the inherent difficulties of obtaining samples on farm, and overcome them. These difficulties include higher cost, the necessity to educate and motivate owners, and counteracting potentially negative socio-economic implications.

Article 3.8.4.2.

Description of cattle subpopulations

1. Cattle over 30 months of age displaying behavioural or clinical signs consistent with BSE (clinical suspects)

Cattle affected by illnesses that are refractory to treatment, and displaying progressive behavioural changes such as excitability, persistent kicking when milked, changes in herd hierarchical status, hesitation at doors, gates and barriers, as well as those displaying progressive neurological signs without signs of infectious illness are candidates for examination. These behavioural changes, being very subtle, are best identified by those who handle animals on a daily basis. Since BSE causes no pathognomonic clinical signs, all countries with cattle populations will observe individual animals displaying clinical signs consistent with BSE. It should be recognised that cases may display only some of these signs, which may also vary in severity, and such animals should still be investigated as potential BSE affected animals. The rate at which such suspicious cases are likely to occur will differ among epidemiological situations and cannot therefore be predicted reliably.

~~This subpopulation, particularly cattle over 30 months of age, is the one exhibiting the highest prevalence. The recognition greatly depends on the owner's awareness and observation of suspect animals. The reporting of these suspect animals when at the farm will depend on the owner's motivation based on cost and socio-economic repercussions.~~ The accurate recognition,

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reporting and classification of such animals will depend on the ongoing owner/veterinarian awareness programme. This and the quality of the investigation and laboratory examination systems (Article 2.3.13.2), implemented by the Veterinary Services, are essential for the credibility of the surveillance system.

2. Cattle over 30 months of age that are non-ambulatory, recumbent, unable to rise or to walk without assistance; cattle over 30 months of age sent for emergency slaughter or condemned at ante-mortem inspection (casualty or emergency slaughter, or downer cattle)

These cattle may have exhibited some of the clinical signs listed above which were not recognised as being consistent with BSE. Experience in countries where BSE has been identified indicates that this subpopulation is the one demonstrating the second highest prevalence. For that reason, it is the second most appropriate population to target in order to detect BSE.

3. Cattle over 30 months of age which are found dead on farm, during transport or at an abattoir (fallen stock)

These cattle may have exhibited some of the clinical signs listed above prior to death, but were not recognised as being consistent with BSE. Experience in countries where BSE has been identified indicates that this subpopulation is the one demonstrating the third highest prevalence.

4. Cattle over 36 months of age at routine slaughter

Experience in countries where BSE has been identified indicates that this subpopulation is the one demonstrating the lowest prevalence. For that reason, it is the least appropriate population to target in order to detect BSE. However, sampling in this subpopulation may be an aide in monitoring the progress of the epizootic and the efficacy of control measures applied, because it offers continuous access to a cattle population of known class, age structure and geographical origin. Testing of routine slaughter cattle 36 months of age or less is of relatively very little value (Table 2).

~~Within each of the above subpopulations, countries may wish to target cattle identifiable as imported from countries or zones not free from BSE, cattle which have consumed potentially contaminated feedstuffs from countries or zones not free from BSE, offspring of BSE affected cows and cattle which have consumed feedstuffs potentially contaminated with other TSE agents.~~

~~When establishing a surveillance strategy, authorities must take into account inherent difficulties of obtaining samples on farm. These difficulties include higher cost, necessity for education and motivation of owners, counteracting potentially negative socio-economic implication. Authorities must find ways to overcome these difficulties.~~

Article 3.8.4.3.

~~4)~~ **Implementation of Type A surveillance**

In order to implement efficiently a surveillance strategy for BSE, a country must use good quality data (or reliable estimates) documented records or reliable estimates of concerning the

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age distribution of ~~it's the~~ adult cattle population and the number of cattle tested for BSE stratified by age and by subpopulation within the country, zone or compartment. ~~The application of the following procedure will allow the detection of BSE at a prevalence of at least one case per 100,000 in the adult cattle population, at a confidence level of 95% in the country, zone or compartment of concern.~~

The approach assigns 'point values' to each sample, based on the subpopulation from which it was collected and the likelihood of detecting infected cattle in that subpopulation. The number of points a sample is assigned is determined by the subpopulation from which the sample is collected and the age of the animal sampled. The total points accumulation is then periodically compared to the target number of points for a country, *zone or compartment*.

~~A country should design its~~ surveillance strategy should be designed to ensure that samples are representative of the herd of the country, *zone or compartment*, and include consideration of demographic factors such as production type and geographic location, and the potential influence of culturally unique husbandry practices. The approach used and the assumptions made should be fully documented, and the documentation retained for 7 years.

The points targets and surveillance point values in this appendix were obtained by applying the following factors to a statistical model:

- a) ~~a the design prevalence for Type A or Type B surveillance of one case per 100,000 of the adult cattle population;~~
- b) a confidence level of 95%;
- c) the pathogenesis, and pathological and clinical expression of BSE:
 - i) sensitivity of diagnostic methods used;
 - ii) relative frequency of expression by age;
 - iii) relative frequency of expression within each subpopulation;
 - iv) interval between clinical pathological change and clinical expression;
- d) demographics of the cattle population, including age distribution;
- e) influence of BSE on culling or attrition of animals from the cattle population via the four subpopulations;
- f) percentage of infected animals in the cattle population which are not detected.

Although the procedure accepts very basic information about a cattle population, and can be used with estimates and less precise data, careful collection and documentation of the data significantly enhance their value. Since samples from clinical suspect animals provide many times more information than samples from healthy or dead-of-unknown-cause animals, careful attention to the input data can substantially decrease the procedure's cost and the number of samples needed. The essential input data are:

- a) cattle population numbers stratified by age;
- b) the number of cattle tested for BSE stratified by age and by subpopulation.

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This Appendix utilises Tables 1 and 2 to determine a desired surveillance points target and the point values of surveillance samples collected.

Within each of the subpopulations above in a country, *zone* or *compartment*, a country may wish to target cattle identifiable as imported from countries or *zones* not free from BSE and cattle which have consumed potentially contaminated feedstuffs from countries or *zones* not free from BSE.

All clinical suspects should be investigated, regardless of the number of points accumulated. In addition, animals from the other subpopulations should be tested.

1. Type A surveillance

The application of Type A surveillance will allow the detection of BSE around a design prevalence¹ of at least one case per 100,000 in the adult cattle population in the country, *zone* or *compartment* of concern, at a confidence level of 95%.

2. ~~Maintenance~~ (Type B) surveillance

The application of Type B surveillance will allow the detection of BSE around a design prevalence of at least one case per 50,000 in the adult cattle population in the country, *zone* or *compartment* of concern, at a confidence level of 95%.

Type B surveillance may be carried out by countries, *zones* or *compartments* of negligible BSE risk status (Article 2.3.13.3) to confirm the conclusions of the risk assessment, for example by demonstrating the effectiveness of the measures mitigating any risk factors identified, through surveillance targeted to maximise the likelihood of identifying failures of such measures.

Type B surveillance may also be carried out by countries, *zones* or *compartments* of controlled BSE risk status (Article 2.3.13.4), following the achievement of the relevant points target using Type A surveillance, to maintain confidence in the knowledge gained through Type A surveillance.

For countries which have demonstrated through risk assessment (including surveillance) that they meet the requirements for 'negligible risk', should continue at a reduced maintenance level.

In order to implement efficiently a maintenance surveillance strategy for BSE, a country must use good quality data (or reliable estimates) concerning the age distribution of its adult cattle population and the number of cattle tested for BSE stratified by age and by subpopulation. The application of the following procedure will allow the detection of BSE prevalence of at least one case per 50,000 in the adult cattle population, at a confidence level of 95% in the country, *zone* or *compartment* of concern. This Appendix utilises Tables 1 and 2 to determine a desired surveillance point target and the point values of surveillance samples collected.

Maintenance surveillance should focus on the higher prevalence subpopulations (especially clinical suspects). The number of clinical suspect samples taken annually should approximate the number of samples taken annually from clinical suspect cases during the time taken to reach the country, *zone* or *compartment's* BSE status (to a maximum of 7 years).

¹ DP (design prevalence) is used to determine the size of a testing survey expressed in terms of target points. If the actual prevalence is greater than the selected design prevalence, the survey is highly likely to detect disease.

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Article 3.8.4.4.

1. Selecting the points target

The ~~desired~~ surveillance points target ~~is~~ should be selected from Table 1, which shows target points for adult cattle populations of different sizes. ~~A country's~~ The size of the adult cattle population size of a country, zone or compartment may be estimated or may be set at one million because, for statistical reasons, one million is the point beyond which sample size does not further increase with population size. ~~The target depends on the design prevalence chosen by the country.~~

Table 1 Points targets for different adult cattle population sizes in a country, *zone* or *compartment* ~~which has not identified any BSE cases~~

Points targets for country, zone or compartment with 0 cases, 95% confidence		
Adult cattle population size (24 months and older)	Type A surveillance	Type B surveillance
≥ 1,000,000	300,000	150,000
800,000 – 1,000,000	240,000	120,000
600,000 – 800,000	180,000	90,000
400,000 – 600,000	120,000	60,000
200,000 – 400,000	60,000	30,000
100,000 – 200,000	30,000	15,000
50,000 – 100,000	15,000	7,500

~~DP is the maximum possible prevalence or “design prevalence”.~~

2. Determining the point values of samples collected

Table 2 can be used to determine the point values of the surveillance samples collected. The approach assigns point values to each sample according to the likelihood of detecting infection based on the subpopulation from which the sample was collected and the age of the animal sampled. This approach takes into account the general principles of surveillance described in Appendix 3.8.1. and the epidemiology of BSE.

Because precise aging of the animals that are sampled may not be possible, Table 2 combines point values into five age categories. The point estimates for each category were determined as an average for the age range comprising the group. The age groups were selected on their relative likelihoods of expressing BSE according to scientific knowledge of the incubation of the disease and the world BSE experience. Samples may be collected from any combination of subpopulations and ages but should reflect the demographics of the cattle herd of the country, *zone* or *compartment*.

If a country, zone or compartment determines, based on the demographics and epidemiological characteristics of its cattle population, that precise classification of the subpopulations ‘casualty

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or emergency slaughter, or downer cattle' and 'fallen stock' is not possible, these subpopulations may be combined. In such a case, the surveillance point values accorded to the combined subpopulation would be that of 'fallen stock'.

~~In addition, Countries should sample at least three of the four subpopulations.~~

The total points for samples collected may be accumulated over a period of a maximum of 7 consecutive years to achieve the target number of points determined in Table 1.

Table 2 Surveillance point values for samples collected from animals in the given subpopulation and age category

Surveillance subpopulation			
Routine slaughter ¹	Fallen stock ²	Casualty slaughter ³	Clinical suspect ⁴
Age ≥ 1 year and < 2 years			
0.01	0.2	0.4	N/A
Age ≥ 2 years and < 4 years (young adult)			
0.1	0.2	0.4	260
Age ≥ 4 years and < 7 years (middle adult)			
0.2	0.9	1.6	750
Age ≥ 7 years and < 9 years (older adult)			
0.1	0.4	0.7	220
Age ≥ 9 years (aged)			
0.0	0.1	0.2	45

¹ See point 4) of Article 3.8.4.2.

² See point 3) of Article 3.8.4.2.

³ See point 2) of Article 3.8.4.2.

⁴ See point 1) of Article 3.8.4.2.

Surveillance points remain valid for 7 years (the 95th percentile of the incubation period).

~~Article 3.8.4.5.~~

~~To monitor the evolution of BSE in a country, zone or compartment once it is detected~~

~~To monitor the evolution of BSE in a country, zone or compartment once it is detected, a more intensive sampling method needs to be used to determine disease prevalence. For countries that have determined that BSE exists within their cattle population, the goal of surveillance shifts from one of detection to one of monitoring the extent and evolution of the disease, and monitoring the effectiveness of control measures such as feed bans and policies for the removal of specified risk materials.~~